

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 01D-0049]

Display Date	3/19/01
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Certifier	<i>[Signature]</i>

**Guidance on Reduction of Civil Money Penalties for Small Entities; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is issuing the final guidance entitled "Reduction of Civil Money Penalties for Small Entities" as required by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) and the Presidential Memorandum of April 21, 1995.

**DATES:** The final guidance is effective *[insert date 30 days after date of publication in the Federal Register]*. Written comments may be submitted at any time.

**ADDRESSES:** Submit written comments on the final guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document. Submit written requests for single copies of the final guidance to the Division of Compliance Policy (HFC-230), Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or fax your request to 301-827-0482. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the final guidance.

**FOR FURTHER INFORMATION CONTACT:** Jeffrey B. Governale, Division of Compliance Policy (HFC-230), Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-0411, FAX 301-827-0482.

**SUPPLEMENTARY INFORMATION:**

*NAD-1*

## I. Background

FDA is issuing a final guidance for the reduction of civil money penalties (CMP's) for small entities (penalty reduction guidance) as mandated by SBREFA (Public Law 104-121) and the Presidential Memorandum of April 21, 1995 (60 FR 20621, April 26, 1995). SBREFA was enacted on March 29, 1996, and seeks to improve the regulatory climate for small entities by, among other things, requiring agencies to establish small entity penalty reduction policies. The Presidential Memorandum of April 21, 1995, directs agencies to use their discretion to modify the penalties for small businesses in certain situations.

FDA currently enforces the following amendments to the Federal Food, Drug, and Cosmetic Act (21 U.S.C.) and the Public Health Service Act (42 U.S.C.), which authorize CMP's under the referenced sections:

Radiation Control for Health and Safety Act of 1968 (21 U.S.C. 360pp),

Safe Medical Devices Act of 1990 (21 U.S.C. 333(f)),

Mammography Quality Standards Act of 1992 and the Mammography Quality

Standards Reauthorization Act of 1998 (42 U.S.C. 263b(h)),

National Childhood Vaccine Injury Act of 1986 (42 U.S.C. 262(d)(2) and 42 U.S.C. 300aa-28),

Prescription Drug Marketing Act of 1988 (21 U.S.C. 333(b)),

Generic Drug Enforcement Act of 1992 (21 U.S.C. 335b), and

Food Quality Protection Act of 1996 (21 U.S.C. 333(f)).

In the **Federal Registers** of May 18 and June 15, 1999 (64 FR 26984 and 32059, respectively), FDA issued a draft civil money penalty reduction policy for small entities. One trade association submitted comments to the docket. FDA reviewed and evaluated all of the comments and, in response, made appropriate changes to the final penalty reduction guidance.

In addition to the comments, SBREFA, and the April 21, 1995, Presidential memorandum discussed above, FDA has reviewed: (1) The Federal statutes it enforces which authorize CMP's,

and (2) its current practices used to assess CMP's on small entities. On the basis of that review, FDA is announcing its final penalty reduction guidance for small entities.

## **II. Statutory and Regulatory Requirements**

This penalty reduction guidance shall not supersede or negate any applicable statutory or regulatory requirements. For example in device and food cases, in determining the amount of a CMP and any modification, the agency shall comply with 21 U.S.C. 333(f). Subsequently, this penalty reduction guidance would then be applied to small entities.

## **III. Significance of Guidance**

This guidance document represents the agency's current thinking on the reduction of CMP's for small entities. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

The agency has adopted good guidance practices (GGP's), which set forth the agency's regulation for the development, issuance, and use of guidance documents (65 FR 56468, September 19, 2000). This final guidance document is issued as a Level 1 guidance consistent with GGP's.

## **IV. Comments**

Interested persons may, at any time, submit to the Dockets Management Branch (address above) written comments on the final guidance document entitled "Reduction of Civil Money Penalties for Small Entities." Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Such comments will be considered when determining whether to amend the current guidance. Copies of the final guidance and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

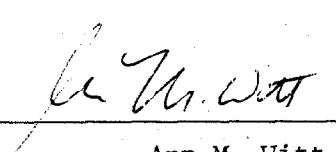
## V. Electronic Access

A copy of the final guidance may also be downloaded to a personal computer with access to the Internet. The Office of Regulatory Affairs' (ORA) home page includes the guidance and may be accessed at <http://www.fda.gov/ora>. The final guidance is available under "Compliance References."

Dated: February 22, 2001  
February 22, 2001.

CERTIFIED TO BE A TRUE  
COPY OF THE ORIGINAL

*Jan Windsor*

  
Ann M. Witt,  
Acting Associate Commissioner for Policy.

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